Press Release

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Daiichi Sankyo Announces Results of Phase 3 Clinical Trial for Anticoagulant Edoxaban (ELDERCARE-AF Study)

Tokyo, Japan (August 31, 2020) – Daiichi Sankyo Company Limited (hereinafter, Daiichi Sankyo) today announced that the primary endpoint has been achieved in the Japan phase 3 clinical trial (ELDERCARE AF Study; hereinafter, the study) for the anticoagulant, edoxaban, in elderly patients with non-valvular atrial fibrillation and high bleeding risk. The results of the study will be presented at the virtual European Society of Cardiology (ESC) Congress 2020, and have already been published online in the New England Journal of Medicine.

The study was a double-blind placebo-controlled study to evaluate the efficacy (prevention of stroke and systemic embolism) and safety (bleeding events, etc.) of edoxaban administered orally at 15 mg once daily in 984 non-valvular atrial fibrillation patients of 80 years and above with a high bleeding risk and who are ineligible for other available anticoagulation therapies.

In the study, the primary endpoint of annual incidence of stroke and systemic embolism was 2.3% in the edoxaban arm and 6.7% in the placebo arm, demonstrating the superiority of edoxaban for the primary efficacy outcome.

The annual incidence of major bleeding, which was a safety evaluation endpoint, was 3.3% in the edoxaban arm vs. 1.8% in the placebo arm, showing a numerically higher rate in the edoxaban arm. However, there was no difference between the treatment arms in fatal bleeding or intracranial bleeding, either of which would be considered to be clinically significant.
No new safety concerns were identified in the study.

Daiichi Sankyo will continue its efforts to provide new treatment options to elderly patients with non-valvular atrial fibrillation.

About EDOSURE – Edoxaban Clinical Research Programme

More than 10 studies, more than 100,000 patients worldwide

Daiichi Sankyo is committed to expanding scientific knowledge about edoxaban, as demonstrated through research programmes evaluating its use in a broad range of cardiovascular conditions, patient types and clinical settings in atrial fibrillation (AF) and venous thromboembolism (VTE) designed to further build on the results of the pivotal ENGAGE AF and Hokusai-VTE studies. More than 100,000 patients worldwide are expected to participate in the edoxaban clinical research programme called EDOSURE, which comprises more than 10 RCTs (randomised, controlled trials), registries and non-randomised clinical studies, including completed, ongoing and future studies. Our goal is to generate new clinical and real-world-data for edoxaban through its use in AF and VTE populations, to provide even greater assurance of its efficacy and safety to physicians and patients worldwide.

The RCTs include:

- ENGAGE AF-TIMI 48 (Effective aNticoaGulation with factor xA next GEneration in Atrial Fibrillation), in AF patients at moderate-to-high risk of thromboembolic events
- Hokusai-VTE (Edoxaban in Venous Thromboembolism), in patients with either acute symptomatic deep vein thrombosis (DVT), pulmonary embolism (PE) or both
- ENSURE-AF (EdoxabaN vs. warfarin in subjectS UndeRgoing cardiovErsion of Atrial Fibrillation), in AF patients undergoing electrical cardioversion
- ENTRUST-AF PCI (EdoxabaN TReatment versUS VKA in paTients with AF undergoing PCI), in AF patients undergoing percutaneous coronary intervention
- Hokusai-VTE Cancer (Edoxaban in Venous Thromboembolism Associated with Cancer), in patients with cancer and an acute VTE event
- ELDERCARE-AF (Edoxaban Low-Dose for EldeR CARE AF patients), in elderly AF patients in Japan
- ELIMINATE-AF (EvaLuatIon of edoxaban coMpared with VKA IN subjects undergoing cAThEter ablation of non-valvular Atrial Fibrillation)
- ENVISAGE-TAVI AF (EdoxabaN Versus standard of care and theIr effectS on clinical outcomes in pAtients havinG undergonE Transcatheter Aortic Valve Implantation (TAVI) - Atrial Fibrillation
- STABLED Study (STroke secondary prevention with catheter ABLation and EDoxaban for patients with non-valvular atrial fibrillation) in Japan

- ENRICH-AF (EdoxabaN foR IntraCranial Hemorrhage survivors with Atrial Fibrillation, an investigator initiated phase III study)

In addition, the global and regional registry and non-randomised clinical studies include those below, which have provided important real-world and clinical data on the use of edoxaban and other oral anticoagulants in everyday practice.

- ETNA-AF (Edoxaban Treatment in routiNe clinical prActice in patients with nonvalvular Atrial Fibrillation)
- ETNA-VTE (Edoxaban Treatment in routiNe clinical prActice in patients with Venous ThromboEmbolism)
- EMIT-AF/VTE (Edoxaban Management In diagnostic and Therapeutic procedures-AF/VTE)
- Prolongation PREFER in AF (PREvention oF thromboembolic events - European Registry) in patients with AF
- ANAFIE (All Nippon AF In Elderly) Registry in Japan
- Cancer-VTE Registry in Japan
- RYOUMA (Real world ablation therapY with anti-cOagUlants in Management of Atrial fibrillation) Registry in Japan
- KYU-RABLE (Multicenter study associated with KYU-shu to evaluate the efficacy and safety of edoxaban in patients with non-valvulaR Atrial fiBriLlation undergoing cathEter ablation) in Japan
- BPV-AF (Atrial Fibrillation with BioProsthetic valve) Registry in Japan

Through EDOSURE, we are committed to adding to our scientific knowledge concerning edoxaban in a variety of AF and VTE patients, including those who are vulnerable.

About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical therapies to improve standards of care and address diversified, unmet medical needs of people globally by leveraging our world-class science and technology. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 15,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for cardiovascular diseases, under the Group's 2025 Vision to become a "Global Pharma Innovator with Competitive Advantage in Oncology," Daiichi Sankyo is primarily focused on providing novel therapies in oncology, as well as other research areas centered around rare diseases and immune disorders. For more information, please visit: www.daiichisankyo.com.